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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,155	11/03/2003	Mark E. Howard	001P0301	3796
7590	12/01/2005		EXAMINER	
Rodney F. Brown 3365 Baltimore Street San Diego, CA 92117			AHMED, AAMER S	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 12/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	10/700,155	Applicant(s)	HOWARD, MARK E.
Examiner	Aamer S. Ahmed	Art Unit	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 11/03/2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-14 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-20 are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 03 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 11/3/2003.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to fluid aspiration device, classified in class 604, subclass 35.
- II. Claims 15-20, drawn to method for aspirating a fluid from a region of a body, classified in class 604, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions fluid aspiration device and method for aspirating a fluid from a region of a body are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. During a telephone conversation with Rodney Brown on July 13<sup>th</sup> 2005 a provisional election was made without traverse to prosecute the invention of fluid aspiration device, claims 1-14. Affirmation of this election must be made by applicant in replying to this Office action. Claim 15-20 are

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Specification***

The disclosure is objected to because of the following informalities: page 11 line 5 has missing text.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Livingstone U.S. Patent Number 1,496,126. As to claim 1, Livingstone ('126) describes a fluid aspiration device comprising: a syringe 2 having an aspiration intake 27 and a fluid chamber 5; an aspiration valve 20 positioned in an aspiration fluid passageway between the aspiration intake 27 and fluid chamber 5 and having an open aspiration position and a closed disposal position, wherein the aspiration valve 20 transitions from a closed disposal position to an open aspiration position in response to fluid pressure directed from the aspiration intake 27 to the fluid chamber 5; a disposal reservoir 16 a disposal fluid passageway 15 between the fluid chamber 5 and the disposal reservoir 16; and a disposal valve 10 positioned in the disposal fluid passageway 15 and having an open disposal position and a closed aspiration position, wherein the disposal valve 10 transitions from a closed aspiration position to an open position in response to fluid pressure directed from the fluid chamber 5 to the disposal reservoir 16, (see figure 1).

As to claim 2 Livingstone ('126) describes that the aspiration valve 20 and disposal valve 10 are mounted in a valve assemble 3 included in the syringe 2 in series between the aspiration intake 27 and fluid chamber 5, (see figure 1).

As to claim 3, Livingston ('126) discloses that the syringe, disposal reservoir 16 and disposal fluid passageway 15 are in fluid isolation from the external environment of the aspiration device see figure 1 and page 1 line 14.

As to claim 4, Livingston ('126) discloses that the aspiration device as described in reference to claim 1 above further comprises fluid-tight connections 26 and 6 and 14 between the aspiration intake 27 and aspiration valve 20, between the aspiration valve 20 and the fluid chamber 5 and the disposal valve 10 and the disposal reservoir 16.

As to claims 5 and 6, Livingston ('126) discloses that the aspiration valve 20 and disposal valve 20 are biased in closed positions page 2 line 103 and page 3 line 3.

As to claim 7, Livingston ('126) discloses that the disposal fluid passageway 15 comprises flexible tubing 15.

Thus Livingstone ('126) reasonably appears to teach and disclose every element of claims 1-7 and therefore anticipates these claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livingston ('126) in view of Hlavinka et al U.S. Patent Number 5,496,301. Livingston ('126) disclose a fluid aspiration device comprising: a syringe 2 having an aspiration intake 27 and a fluid chamber 5; an aspiration valve 20 positioned in an aspiration fluid passageway between said aspiration intake 27 and said fluid chamber 5 and having an open aspiration position and a closed disposal position, wherein said aspiration valve 20 transitions from said closed disposal position to said open aspiration position in response to fluid pressure directed from said aspiration intake to said fluid chamber 5; a disposal reservoir 16; a disposal fluid passageway 15 between said fluid chamber 5 and said disposal reservoir 16; a disposal valve 10 positioned in said disposal fluid passageway 15 and having an open disposal position and a closed aspiration position, wherein said disposal valve 10 transitions from said closed aspiration position to said open disposal position in response to fluid pressure directed from said fluid chamber 5 to said disposal reservoir 16. Moreover Livingston ('1236) discloses that the aspiration valve 20 and the disposal valve 10 are mounted in a valve assemble 3 included in the syringe in series between the aspiration intake 27 and the fluid chamber 5; that the syringe, disposal reservoir 16 and disposal fluid passageway 15 are in fluid isolation from the external environment of the device and have fluid tight connections between the components see figure 1 and page 1 line 14. Furthermore, Livingston ('126) discloses that the aspiration valve 20 and disposal valve 20 are biased in closed positions page 2 line 103 and page 3 line 3. In addition Livingston ('126) discloses that

the device comprises a junction fitting 14 and a reservoir connector 18, wherein the disposal fluid passageway 15 comprises a disposal line see figure 1, the junction fitting 14 and reservoir connector 18 in series see figure 1.

Livingstone ('126) fails to disclose a sampling outlet; a sampling fluid passageway nor that these components are in fluid isolation from the external environment of the device and have fluid tight connections between them, nor does Livingstone ('126) disclose that the sampling fluid passageway comprises a sampling line.

Hlavinka ('301) describes a similar fluid collection system which includes a sampling outlet 22; a sampling fluid passageway 27 between the disposal reservoir 1 and the sampling outlet 22; and a sampling valve 28 positioned in said sampling fluid passageway 27 and having an open sampling position and a closed non-sampling position, wherein said sampling valve 28 prevents fluid communication between said disposal reservoir 1 and said sampling outlet 22 in said closed non-sampling position and enables fluid communication between said disposal reservoir 1 and said sampling outlet 22 in said open sampling position. Moreover Hlavinka ('301) teaches that the sampling outlet 22 and sampling fluid passageway 27 are in fluid isolation from the external environment of the device and have fluid tight connections between the components col. 2 line 55 and that the sampling fluid passageway 27 comprises a sampling line see figure 6.

It would have been obvious to one of ordinary skill in the art at the time of invention by the applicant to modify the fluid collection device of Livingstone ('126) by

adding a fluid tight sampling component in the manner suggested by Hlavinka ('301) in order to permit the fluid collection device of Livingstone to provide a safe and efficient method for removing biological fluids samples during collection without opening the closed collection system (Hlavinka '301 col. 2 line 28).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4215476 A	Armstrong; Alexander S.
WO 9003194 A1	ARNSTEIN, FRANCIS EMANUEL et al.
US 5038938 A	Berndt; Dieter R.
EP 358429 A2	BORSANYI, ALEXANDER et al.
US 5098377 A	Borsanyi; Alexander et al.
US 4210173 A	Choksi; Pradip V. et al.
US 20010049486 A1	Evans, Michael A. et al.
US 4857063 A	Glenn; Luke H.
US 5356375 A	Higley; Robert E.
US 5685875 A	Hlavinka; Dennis J. et al.
US 6290690 B1	Huculak; John C. et al.
US 6790196 B2	Kokane; Jaydeep Y. et al.
US 20030207464 A1	Lemmo, Tony et al.
US 4838855 A	Lynn; Lawrence A.
US 5531672 A	Lynn; Lawrence A.
US 5549651 A	Lynn; Lawrence A.
US RE37357 E	Lynn; Lawrence A.
US 5324256 A	Lynn; Lawrence A. et al.
US 5447495 A	Lynn; Lawrence A. et al.
US 5466219 A	Lynn; Lawrence A. et al.
US 20030176813 A1	Mathias, Jean-Marie et al.
US 6520948 B1	Mathias; Jean-Marie et al.
US 4112947 A	Nehring; John R.
US 4957491 A	Parker; Richard D.
US 6027490 A	Radford; Fred R. et al.
US 4729401 A	Raines; Kenneth C.
US 4824434 A	Seitz, Jr.; H. Michael
US 6364847 B1	Shulze; John E. et al.
US 6632203 B2	Swisher; David Rork et al.
US 4958621 A	Topel; Howard C. et al.
US 3957052 A	Topham; Silas Charles
US 2357238 A	TRIMBLE AVERAL T

Art Unit: 3763

US 4051852 A	Villari; Frank K.
US 4702733 A	Wright; George M. et al.
US 4493694 A	Wuchinich; David G.
US 20020007139 A1	Zaias, Nardo et al.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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